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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,795	11/23/2001	George Jackowski	2132.105	5610

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MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER
DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,795	Applicant(s) JACKOWSKI ET AL.	
	Examiner Deborah A Davis	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice to Comply with Seq. Rules

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:1, classified in class 530, subclass 300.

   II. Claims 1-2, drawn to a biopolymer, comprising SEQ ID NO: 2, classified in class 530, subclass 300.

   III. Claims 1-2, drawn to a biopolymer, comprising SEQ ID NO: 3, classified in class 530, subclass 300.

   IV. Claims 3-9, drawn to a method for categorizing a disease state, classified in class 424, subclass 93.1.

   V. Claims 10-28, drawn to a diagnostic assay kit, classified in class 422, subclass 61.

   VI. Claims 29-32, drawn to polyclonal antibodies, classified in class 436, subclass 547.

   VII. Claims 33-37, drawn to a method for identifying a therapeutic process related to a disease state, classified in class 435, subclass 7.1.

   VIII. Claim 38, drawn to a method for regulating a disease state, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are drawn to two disclosed patenably distinct inventions as evidenced by their different SEQ ID Nos I, 2 and 3. The three products are independent and require different searches. These separate products bear distinct structural or biochemical properties. Therefore, each disclosed patentably distinct composition/product is considered a separate invention.

3. Inventions (I-III) and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions (I-III) can be used by any of the methods of inventions V, VII or VIII.

4. Inventions (1-III) and V are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is drawn to a biopolymer marker comprising SEQ ID NO: I; Invention II is drawn to a biopolymer marker comprising SEQ ID NO: 2; Invention III is drawn to a biopolymer marker comprising SEQ ID NO: 3; Invention V is drawn to a diagnostic kit comprising various samples and a solid support. Therefore, each disclosed patentably distinct product is considered a separate invention.

5. Inventions (I-III) and VI are drawn to four disclosed patentably distinct inventions (compositions comprising materially different limitations). Invention (VI) is directed to an antibody with the specificity for the biopolymers. The two products are independent and require different searches. These separate product/composition bear distinct structural or biochemical properties. Therefore, each disclosed patentably distinct composition is considered a separate invention.

6. Inventions (I-III) and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of inventions (I-III) can be used by any of the methods of groups IV, V, and VIII.

7. Inventions (I-III) and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention (I-III) can be used by any of the methods of inventions IV, V, and VII.

8. Inventions IV, VII and VIII are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, because invention IV is drawn to a method for categorizing a disease state, invention VII is drawn to a method for identifying a therapeutic process related to a disease state, and invention VIII is drawn to a method of regulating a disease state. Therefore, each disclosed patentably distinct method is considered a separate invention.

9. Inventions VI and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention VI can be used by any of the methods of invention V, VII and VIII.

10. Inventions V and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the kit can be used by any of the methods of inventions VII or VIII.

11. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention V is drawn to a diagnostic kit comprising various samples and a solid support, invention VI is drawn to polyclonal antibodies. Therefore, each disclosed patentably distinct product is considered a separate invention.

12. Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit can be used by any of the methods of inventions IV or VIII.

13. Inventions V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the kit can be used in any of the methods of inventions IV or VII.

14. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention VI can be used in any of the methods of inventions IV, V and VIII.

15. Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention VI can be used by any of the methods of inventions IV, V, and VII.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Please note that classifications in the restriction are illustrative only and do not represent all the classes and subclasses which must be searched for each invention; nor is the search limited to

issued US patents, but rather includes foreign patents and applications as well as literature searches, therefore restriction for examination purposes as indicated proper.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
July 14, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
07/14/03